REMARKS

Reconsideration and allowance of the application are respectfully requested.

Claims 1, 7, 8, 27, 31, 49 and 50 have been canceled.

Claims 2-8 have been amended to correct the informalities noted on Page 2 of the Office Action. Claims 6, 20, 28, 40, 49 and 53 have been amended. The allowance of Claims 21-26, 35-39 and 41-48 is noted and appreciated. Claims 2-6, 9, 11, 14, 18, 30, 32-34 and 52 have been rewritten into independent form and hence should be allowable as indicated in the Office Action. New independent Claim 54 and its dependent Claims 55-58 have been added and new independent Claim 59 has been added along with its dependent Claims 60-62. Claims 20 and 53 should be allowable as their respective dependencies have been changed from a rejected claim to an allowed or found to be allowable claim.

With respect to the informalities set forth on Page 2 of the Office Action and Claim 1, an antecedent for "the imaging area" has been inserted in the preamble of each of the claims originally dependent on Claim 1. In Claim 2, Line 3, "a paddle" has been changed to -- the paddle --. In Claim 3, Line 5, "it has been changed to -- paddle --. In Claim 3, Line 6, "the tilt angle" has been changed to -- a tilt angle --. In Claim 5, Line 9, "the support" has been changed to -- a support --. The correction of these claim informalities has also been made in the rewritten dependent claims that were previously objected to.

Turning now to the 35 U.S.C. 102 rejection beginning on Page 2 of the Office Action, Claims 1, 7-8 and 27 have been canceled.

With respect to the rejection of Claims 20 and 31 over Niklason and Barbarisi, Claim 31 has been canceled and Claim 20 has been amended to depend on allowable Claim 19.

The illustrated embodiment of the invention is a commercially available product from the Assignee of this application and provides enhanced mammogram images over that of the conventional parallel, flat paddle, shortcomings of which are discussed beginning on Page 5, Line 29, et seq. In this regard, the inventor has provided Exhibit A attached hereto which illustrates and compares a mammogram in Figure 1 taken using the illustrated embodiment of this invention versus an inferior mammogram shown in Figure 2 taken with the conventional flat panel taken of the same patient. Figures 1 and 2 are mediallateral oblique views as stated by the inventor in Exhibit A. Figure 3 in Exhibit A is a mammogram taken using the illustrated embodiment of this invention and is superior to the mammogram of Figure 4 which used the conventional, flat panel. The written description relating to Figures 1-4 in Exhibit A are the inventor's own word

description which was provided to the undersigned for inclusion as Exhibit A. As stated on Page 5, Lines 1-5 of this application, the device of Niklason, U.S. Patent No. 5,506,877, has not been commercially marketed, or is not commercially distributed to the extent that is a known commercially competitive product to the illustrated embodiment of the invention insofar as can be ascertained by the inventor even through the patent application. Hence, the inventor does not have a Niklason paddle to do any testing. The shortcomings of the Niklason paddle are set forth on Pages 5-8 of this patent application and the Niklason patent is distinguished therein and hereinafter.

Claim 28 has been amended. Amended Claim 28 is submitted to be patentable over Niklason in that it recites a flexible portion that is pivotable from a first position relative to the fixed horizontal portion of the paddle to a second inclined position relative to the fixed horizontal portion and that the pivot location is an end of the fixed horizontal portion at a pivot location substantially outwardly of the chest wall. This structure is not found in Niklason. The pivot connection 52 of the rigid paddle 48 (Figures 4-8B) of Niklason is at the sides of the compression paddle 48 and pivot the entire paddle 48 within the support frame 46 as clearly shown in Figure 6A. Moreover, in the Figure 4-8b embodiment, the posterior chest wall section 48C is fixed in its relationship to the anterior section 48a and there is no pivot therebetween that allows the anterior section 48a to pivot from a first position to a second inclined position with respect to the fixed horizontal portion, as recited in Claim 28. The paddle 48 in Figures 1-3 of Niklason has a pivot connection 52 at the chest wall and the chest wall portion 48b of the paddle is vertical rather then being claimed substantially horizontal portion. Claim 28 recites that the horizontal fixed portion projects substantially outwardly of the chest wall to apply a first compressive force and that the paddle provides the second force with a horizontal force component that is less than first force. The Niklason paddle of Figures 1-3 lacks a fixed substantially horizontal portion extending outwardly from the chest wall to compress the breast tissue outwardly of the chest wall to lessen a subsequent pushing of the breast tissue into the chest wall. This lessening of breast tissue being pushed back into the chest wall has been found to allow lesions to be imaged on the breast at the chest wall, where a large number of lesions occur, where they have not imaged before using conventional paddles; see the Livingston Affidavit being submitted herewith. As stated above, in the Figures 3-8 embodiment of Niklason, the paddle portions 48a and 48b are fixed relative to one another and there is lacking any pivoting of the flexible portion relative to the fixed portion to change its angle of inclination with respect to a substantially horizontal fixed portion as recited in Claim 28. Moreover, in Paragraph 5 on Page 9 of the Official Action, it is indicated that the prior

art fails to teach, inter alia, a breast compression paddle having a flexible section extending from a fixed section for compression of the breast as is now recited in Claim 28. Hence, it is submitted that because Niklason lacks the structure and functions recited in Claim 28. Moreover because Niklason neither addresses nor solves the problem of finding lesions at the chest wall or the structure recited in Claim 28, it is submitted that Claim 28 is patentable over Niklason.

Claim 29 depends on Claim 28 and adds a hinge that is x-ray transparent and, hence, is allowable with Claim 28 for this additional reason.

Amended Claim 40 is submitted to be patentable over Virta, U.S. Patent No. 5,050,197, in that Claim 40 recites a pivot connection between the frame and the bucky and a bucky which pivots about this pivot connection toward the paddle to provide an extended area of breast compression between the paddle and the pivoted bucky whereas in Virta, the lower bucky 7 is fixed to the frame part 2 and only the upper paddle 6 is pivoted. As described in Column 3, Line 24 of Virta, when the breast is compressed as shown in Figure 3, the upper paddle 6 is in the horizontal position parallel to the bucky 7. Thus, the bucky is never pivoted about a pivot connection to a frame in order to compress the breast. In Virta, the entire frame part 2 with the buckey may be rotated along with the paddle to a vertical position, but this rotation is to change from a vertical imaging to a horizontal imaging and is not pivoting the bucky to compress the breast as recited in amended Claim 40. Moreover, Claim 40 should be allowable for the reasons given the allowable subject matter in the Office Action on Page 9, Paragraph 4. Thus, it is submitted that Claim 40, as amended, is patentable over Virta.

Claim 51 has been amended to recite that the x-ray transparent hinge extending over the breast allows relative movement between the posterior section and the anterior section and that:

1) the posterior fixed section extends outwardly of the chest wall;
2) the x-ray transparent hinge is located outwardly of the chest wall; and
3) the anterior section is joined to and extends from the posterior fixed section at a location outwardly of the chest wall.

In Figures 1-3 of Niklason, the hinge 52 is at the chest wall vertical portion 48 of the paddle. This posterior paddle portion 48b does not extend outwardly from the chest wall to compress the breast tissue and the hinge connection 52 is at the chest wall rather spaced outwardly of the chest wall as recited in Claim 51. The hinge connection 52 in the Figure 4-8 embodiment is located outwardly of the x-ray beam imaging area and (as recited in Claim 51) lacks:

> "the hinge extending over the breast and allowing x-rays to pass through the hinge section without causing a shadow on the x-ray image of the breast"

Moreover, the hinge section 52 shown in Figure 6a does not hinge the anterior and posterior sections for relative movement to each other whereas Claim 51 recites that the hinge provides relative movement of the posterior and anterior sections relative to one another. Niklason never addressed nor solved the problems of compressing the breast outwardly of the chest wall and providing an x-ray transparent hinge in the imaging area. In any event, Claim 51, as amended, should be allowable for the same reasons given on Page 9, Paragraph 5 of the Official Action. Hence, it is submitted that Claim 51 is patentable over Niklason.

Claim 54 and its dependent Claims 55-58 are submitted to be patentable over Niklason et al in that Claim 54 recites an x-ray transparent, flexible hinge portion covering the breast between the anterior and posterior sections of the breast and in that the flexible hinge section allows the anterior and posterior sections to change the angle of inclination between the anterior and posterior sections for compression of the respective anterior and posterior sections of the breast. Because of these difference in structure and the function of how the breast is compressed as set forth in Claim 54 and in Niklason et al., it is submitted that Claim 54 and the dependent claims are patentable over Niklason.

Claim 55 adds to Claim 54 that the hinge section covering a portion of the breast intermediate the posterior and anterior breast portions is a living hinge made of the same plastic as the posterior and anterior sections. The pivot pins 52 (Figure 6A) do not cover the breast and are not a living hinge of plastic. Hence dependent Claims 55 is allowable for this additional reason.

Dependent Claim 56 adds to Claim 54 that posterior section extends outwardly from the chest wall for a distance of a few centimeters and then joins the hinge section. This structure lessens displacement of this posterior breast tissue into the chest wall by the inclined anterior section compression of the anterior breast tissue. In Figures 1-3 of Niklason, the hinge section is at the chest wall and, hence, lacks the structure and the functions set forth in Claim 55. In Figures 4-8 of Niklason, there is no hinge between the posterior 48c and anterior portion 48a. Hence, Claim 55 is patentable for this additional reason.

Dependent Claim 57 is directed to an x-ray transparent hinge which is not only transparent to x-rays while covering a portion of the breast, but meets governmental regulations in

that it is thin and meets the paddle thickness requirement of about 0.075 to 0.095 inch, which is not met by the pivot pin connection 52 of Niklason et al.

Method Claim 59 and its dependent Claims 60-62 are submitted to be patentable over Niklason in that it recites a anterior section that is moveable at a common point relative to the posterior portion and that their juncture is at a common point which is located at least several centimeters outwardly of the chest wall. In Figures 1-3 of Niklason, the pivot connection is at the chest wall and is not spaced outwardly of the chest wall. In the Figures 4-8 embodiment of Niklason, the posterior and anterior portions are rigid and there is no moving of the second portion relative to the first section much less for any reason much less at a location several centimeters outwardly of the chest wall and no moving of the anterior portion relative to the posterior portion while holding the posterior breast tissue with a sufficient force to lessen displacement of the posterior breast tissue into the chest wall. Thus, it is submitted that Claim 59 and its dependent Claims 60-62 are patentable over Niklason.

In view of the foregoing, it is submitted that the application is in condition for allowance which is respectfully requested.

Respectfully submitted,

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